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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/647,726	12/04/2000	Kevin R Stone	56290-054	2424

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EXAMINER	
AFREMOVA, VERA	
ART UNIT	PAPER NUMBER
1651	9

DATE MAILED: 05/13/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/647,726	Applicant(s) Stone et al.
	Examiner Vera Afremova	Art Unit 1651

-- The MAILING DATE f this communication appears on the c ver sheet with the c rrespondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) ☒ Responsive to communication(s) filed on *Mar 10, 2003*.

2a) ☒ This action is **FINAL.** 2b) ☐ This action is non-final.

3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

4) ☒ Claim(s) *1-48* is/are pending in the application.

4a) Of the above, claim(s) _____ is/are withdrawn from consideration.

5) ☐ Claim(s) _____ is/are allowed.

6) ☒ Claim(s) *1-48* is/are rejected.

7) ☐ Claim(s) _____ is/are objected to.

8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

9) ☐ The specification is objected to by the Examiner.

10) ☒ The drawing(s) filed on *12/00/2000* is/are a) ☒ accepted or b) ☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) ☐ All b) ☐ Some* c) ☐ None of:

1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

a) ☐ The translation of the foreign language provisional application has been received.

15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____
4) ☐ Interview Summary (PTO-413) Paper No(s). _____
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

DETAILED ACTION

Claims 1-48 as amended [Paper No. 8 filed 3/10/2003] are pending and under examination.

Response to Arguments

Applicants' arguments filed 3/10/2003 [Paper No. 8] have been fully considered but they are not found persuasive for the reasons below.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

1. Claims 1-48 as amended remain rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-19, 21-40, 42-51 and 53-59 of U.S. Patent No. 6,231,608 [A] in view of Merck Index as explained in the prior office action and for the reasons below.

2. Claims 1-48 as amended remain rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-37 of U.S. Patent No. 6,210,440 [B] as explained in the prior office action and for the reasons below.

3. Claims 1-48 as amended remain rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-28 of U.S. Patent No. 6,402,783 [C] or over claims 1-22 of U.S. Patent No. 5,944,755 [IDS-A33] in view of Merck Index as explained in the prior office action and for the reasons below.

4. Claims 23-48 as amended remain rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-17 of U.S. Patent No. 5,922,027 [IDS-A32] as explained in the prior office action and for the reasons below.

5. Claims 1-22 as amended remain rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-6 of U.S. Patent No. 5,782,915 [IDS-A28] as explained in the prior office action and for the reasons below.

6. Claims 1-48 as amended remain rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-19 of U.S. Patent No. 6,110,206 [IDS-A37] as explained in the prior office action and for the reasons below.

7. Claims 1-48 as amended remain rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-36 of U.S. Patent No. 6,049,025 [IDS-A36] as explained in the prior office action and for the reasons below.

Applicants argue that claims 1, 13, 23, 35 and 45 have been amended to recite a range of glycosidase concentration from about 100 mU/ml to about 200 mU/ml which is argued as being "similar" to the advantageous test conditions of the example 2 (response page 5, par. 1) and which is narrower than the originally claimed range 1-1000 mU/ml.

However, the example 2 demonstrates the use of the whole range 50-300 mU/ml which is broader than the presently claimed range. Moreover, this broad glycosidase concentration range of 5-300 mU/ml is demonstrated as suitable in the claimed invention as disclosed in the example 2 and it is argued as being "similar". Thus, the use of a range which is broader than the presently claimed and which is also taught in the cited patents above, for example: US 6,210,440 [B] (see claim 1 or example 2) or 6,049,025 [IDS-A36] (see claim 1 or example 2) is reasonably believed

to be also suitable and/or similar in the methods for preparing a bone xenograft and for the bone xenografts made by the methods. In addition, it is also noted that the cited patents discloses the use of glycosidase concentration 100 mU/ml to 200 mU/ml which is identical to the presently claimed, for example: see US 6,210,440 [B] at col. 6, line 62; see 6,049,025 [IDS-A36] at col. 7, line 61. Therefore, there are no unobvious differences as argued and the inventions as claimed are co-extensive.

Accordingly, the claimed methods and products of the issued patents US 6,231,608 [A], US 6,210,440 [B], US 6,402,783 [C], US 5,944,755 [IDS-A33], US 5,922,027 [IDS-A32], US 5,782,915 [IDS-A28], US 6,110,206 [IDS-A37] and US 6,049,025 [IDS-A36] and the claimed methods and products of the present invention are obvious variants.

Claim Rejections - 35 USC § 103

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 1-48 as amended remain rejected under 35 U.S.C. 103(a) as being obvious over US 6,110,206 [IDS-A37], US 5,944,755 [IDS-A33], US 5,782,915 [IDS-A28] and US 5,922,027 [IDS-A32] taken with Merck Index as explained in the prior office action and for the reasons below.

Claims are directed to methods of making xenografts and xenograft products intended for human transplantation wherein the xenografts comprise "bone" or "a portion of bone tissue" of

non-human animal and wherein the xenografts are treated with glycosidase at concentration 100 mU/ml to 200 mU/ml and with capping molecules. Some claims are/are further drawn to the use of capping molecules such as sialic acid molecules. Some claims are further drawn to the use of particular concentrations of sialic acid for treatment of xenografts. Some claims are further drawn to the use of glycosidase such as galactosidase, to the use of particular concentration of glycosidase, to the freeze/thaw cycles or gamma irradiation for cellular disruption, to the use of cross linking agents in the methods for making xenografts and xenograft products.

The applied references US 6,110,206 [IDS-A37], US 5,944,755 [IDS-A33], US 5,782,915 [IDS-A28] and US 5,922,027 [IDS-A32] are relied upon as explained in the prior office action.

Applicants argue that claims 1, 13, 23, 35 and 45 have been amended to recite a particular range of glycosidase concentration from about 100 mU/ml to about 200 mU/ml which is argued as being "similar" to the advantageous test conditions identified in the example 2 (response page 5, par. 2). However, the example 2 (specification page 17) demonstrates the use of glycosidase concentration such as 50-300 mU/ml which is broader than the presently claimed glycosidase concentration 100-200 mU/ml, wherein the broad concentration range is taught and demonstrated as suitable in the claimed methods for making xenografts and xenograft products made by method. Thus, there is a reasonable believe that the limitation drawn to the use of a particular concentration of glycosidase for removing from mammalian cells the epitopes responsible of immune response and xenograft rejection is either not critical or it would be within the purview

of one having ordinary skill in the art to adjust concentration of reagents with respect to amounts of material under treatment in the claimed methods for making xenografts and for xenograft products made by method.

It has been noted in the prior office action that the applied references US 6,110,206 [IDS-A37], US 5,944,755 [IDS-A33], US 5,782,915 [IDS-A28] and US 5,922,027 [IDS-A32] have a common inventor with the instant application. Based upon the earlier effective U.S. filing date of the reference, they constitute prior art under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 103(a) might be overcome by: (1) a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not an invention "by another"; (2) a showing of a date of invention for the claimed subject matter of the application which corresponds to subject matter disclosed but not claimed in the reference, prior to the effective U.S. filing date of the reference under 37 CFR 1.131; or (3) an oath or declaration under 37 CFR 1.130 stating that the application and reference are currently owned by the same party and that the inventor named in the application is the prior inventor under 35 U.S.C. 104, together with a terminal disclaimer in accordance with 37 CFR 1.321(c). For applications filed on or after November 29, 1999, this rejection might also be overcome by showing that the subject matter of the reference and the claimed invention were, at the time the invention was made, owned by the same person or subject to an obligation of assignment to the same person. See MPEP § 706.02(l)(1) and § 706.02(l)(2).

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL.** See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Vera Afremova whose telephone number is (703) 308-9351. The examiner can normally be reached on Monday to Friday from 9:00 to 5:30. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Wityshyn, can be reached on (703) 308-4743. The fax phone number for this Group is (703) 308-4242.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Vera Afremova,
Art Unit 1651
May 6, 2003.

IRENE MARX
PRIMARY EXAMINER

Specification.

Please, insert at the beginning of the specification a statement for proper identification of priority benefits. For example: "This application is a 371 of PCT/US__/_____, filed_____, which claims priority to U.S. Provisional application Serial No. 60/_____, filed _____. "